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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,106	09/15/2000	Colin Anthony Kemp	T2328-906561	5597

7590 03/11/2002
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EXAMINER

BAWA, RAJ

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,106

Applicant(s)

Kemp

Examiner

Bawa

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 9, 11, and 12 is/are rejected.
- 7) ☒ Claim(s) 8 and 10 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

D tailed Action

1. Applicant's election without traverse of claims 1 and 4-12 in Paper No. 6 is acknowledged.

Cancellation of all non-elected claims is requested to enhance prosecution.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 7-13 have been renumbered as 6-12 respectively.

4. Claims 8 and 10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8 and 10 not been further treated on the merits.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-7, 9 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 1, 4-7, 9 and 11-12 provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1, 4-7, 9 and 11-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

(ii) Claim 5 is confusing.

(iii) The term "the lactose" lacks a clear antecedent basis.

(iv) Please amend claim 10 by removing the parentheses.

(v) Claim 1 recites improper Markush language. Employ the language "... selected from the group consisting of ... and"

In view of the above statements, it is the Examiner's position that the claims do not meet the threshold requirement of clarity and precision and are not in compliance for definiteness of 35 U.S.C. 112, second paragraph. Note that definiteness of the claims is important to allow others who wish to enter marketplace to ascertain the boundaries of protection that are provided by the claims (*Ex parte Kristensen* 10 USPQ2d 1701, 1703).

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6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7, 9 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Martindale (Ref U) in view of Panoz (USP 4,822,617).

Each and every element of the above-mentioned claims is either identically disclosed by the cited art or clearly inherent to the disclosure thereof. Ref U clearly discloses nitroglycerin (glyceryl trinitrate) ointments to treat impotence (see page 876, left column, paragraph headed "Impotence", lines 1-6). Nitro-Bid is a known proprietary preparation (p.876, right column, last paragraph) which contains lactose, lanolin, petrolatum (e.g., Panoz, col. 3, lines 66 to col. 4, line 2). Ref U also specifically states that nitroglycerin may be employed for treating erectile dysfunction and should be preferably used in conjunction with a condom (p. 876, left col, lines 10-12).

Additionally note that (i) a comprising-type language does not exclude other steps, elements or materials. *Cues Inc. vs. Polymer Industries*, USPQ2d 1847 (DC ND GA 1988); (ii) it is well established that the claims are given the broadest interpretation during examination; and (iii) references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 U.S.P.Q. 545 (CCPA 1969).

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In light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been anticipated within the meaning of 35 U.S.C. 102(b).

No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raj Bawa whose telephone number is (703) 308-2423. The examiner can normally be reached on Tuesday to Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Bawa/LR

February 25, 2002



RAJ BAWA, Ph.D.
PRIMARY EXAMINER